

REMARKS

This Response is timely filed within three months of the mailing date of the latest Office Action. Accordingly, no fee is required. 37 CFR § 1.134-1.136.

Claims 1-32 are pending in this application, and Claim 28 is withdrawn. Claim 21 is amended, and Claims 29-32 are added. Support for the amendment is found in the Specification, *inter alia*, at Paragraph [0054]. No new matter has been added. Reconsideration of the claim rejections in view of the following remarks is respectfully requested.

I. The Claims are Patentable over U.S. Patent No. 4,832,692 to Box et al. in view of U.S. Patent No. 6,783,515 to Miller et al.

The Office rejected Claims 1-22 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,832,692 to Box et al. (hereinafter "Box") in view of U.S. Patent No. 6,783,515 to Miller et al. (hereinafter "Miller"). This rejection is respectfully traversed.

Claim 1 recites a system for percutaneous delivery of bone cement during a surgical procedure, comprising: a plunger assembly, comprising: a shaft having a first end, a middle section, and a second end, wherein the middle section is threaded; and a handle attached to the first end of the shaft; a dispenser hub assembly around the shaft, the dispenser hub assembly having a collar and a hand-grip attached to the collar, and a threaded portion formed on an interior surface of the collar; and a hollow tube for containing the bone cement during the surgical procedure having a first end and a second end, said first end of said hollow tube adapted to be removably engaged with the threaded portion of the dispenser hub assembly, wherein the shaft is axially

displaceable through the hollow tube for controlled displacement of the bone cement through the second end of the hollow tube. Claims 2-16 depend from Claim 1 and include at least all of the limitations set forth therein.

Claim 17 recites a cement dispensing apparatus for percutaneous delivery of bone cement from a disposable hollow tube to a patient during a surgical procedure, the apparatus comprising: actuation means, comprising: a shaft having a first end, a middle section, and a second end; and a handle attached to the first end of the shaft; and a dispenser hub assembly, around the shaft of the actuation means, the dispenser hub assembly having a collar and a hand-grip attached to the collar, and a threaded portion formed on an interior surface of the collar adapted to receive the disposable hollow tube. Claims 18-20 depend from Claim 17 and include at least all of the limitations set forth therein.

As amended, Claim 21 recites a multi-use cement dispenser kit, comprising: cement delivery means for delivering bone cement into a patient during a surgical procedure, the cement delivery means comprising: a plunger assembly, having a shaft and a handle attached to one end of the shaft; and a dispenser hub assembly, around the shaft of the plunger assembly; and at least one tube pre-filled with bone cement for use during the surgical procedure, the tube adapted to be removably attached to the dispenser hub assembly, wherein the shaft of the cement delivery means is axially displaceable through the tube for controlled displacement of the bone cement through the tube. Claim 22 depends from Claim 21 and includes at least all of the limitations set forth therein.

Taken alone, or in combination, neither Box nor Miller teach or suggest Applicant's claimed invention. Box is directed to an inflation device for inflating and deflating an angioplasty balloon. See Box, Col. 1, ll. 8-14. The device disclosed in Box includes an unthreaded support housing **15** and a threaded half nut member **41**. See Box, Col. 4, ll. 30-60; Col. 5, ll. 35-64; Fig. 2-3. A piston **54** is adapted to disperse a volume of saline solution through a syringe. *Id.* Miller is directed to a specific system for delivering material to a patient. See Miller, Col. 5, ll. 5-15; Col. 7, ll. 45-65. The device in Miller includes first **30** and second columns **36** which may be rotated to advance a piston **44** that displaces a material such as bone cement. *Id.* The devices disclosed in Box and Miller do not, however, disclose a system for delivery of bone cement comprising: a plunger assembly; a dispenser hub assembly around a shaft, having a collar and a hand-grip attached to the collar, and a threaded portion formed on an interior surface of the collar; and a hollow tube for containing bone cement during the surgical procedure, as presently claimed. Moreover, both Box and Miller are silent as to the use of a multi-use kit for delivery bone of cement and do not disclose or suggest a kit having at least one tube pre-filled with bone cement for use during a surgical procedure, as presently claimed.

Further, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify or combine Box and/or Miller. First, the Examiner does not provide any authority in Box to combine with the device disclosed in Miller, and vice versa. Second, the two references are directed to entirely different medical fields. Box is directed to a device for inflating

and deflating a balloon in a patient's vessels during an angioplasty procedure. See Box, Col. 1, ll. 8-65. Miller is directed to a device for injecting hard tissue implant materials. See Miller, Col. 1, ll. 5-10. The subject matter disclosed in the two references are so distinct that each is classified in an entirely different sub-class at the Patent Office. One would not expect a practitioner in the cardiology arts to look for solutions and designs in the orthopedic arts.

For at least these reasons, Applicant respectfully submits that Box and Miller, taken alone or in combination, fail to disclose Applicant's claimed invention. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

II. Claims 23-27 Are Patentable Over the Other Cited References

Claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Box and Miller in view of U.S. Patent 4,583,974 to Kokernak. Claims 24-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Box and Miller in view of U.S. Patent No. 6,749,595 to Murphy. Claim 27 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Box, Miller, and Murphy in view of U.S. Patent No. 4,444,560 to Jacklich. These rejections are respectfully traversed.

Each of Claims 23-27 depends from independent Claim 21 and includes all of the limitations set forth therein. Accordingly, for at least the reasons stated above with respect to Box and Miller, Kokernak, Murphy, and Jacklich do not teach or suggest the invention as presently claimed.

Although three, and as many as four, references are combined in the rejection of Claims 23-27, the Examiner fails to cite one reference that suggests the claimed subject

matter. Each of the numerous cited references – Box, Miller, Kokernak, Murphy, and Jacklich – is silent as to the use of a multi-use kit for delivery of bone cement. Moreover, none of the references discloses or even suggests a kit having at least one tube pre-filled with bone cement for use during a surgical procedure.

There is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify or combine Box and Miller, with Kokernak, Murphy, and/or Jacklich. The Examiner does not provide any authority in Box and Miller to combine with the device disclosed in the respective secondary reference, and vice versa. In addition, the references are directed to entirely different medical fields. Box, Kokernak, and Murphy are classified in entirely different sub-classes at the Patent Office. Only Miller and Jacklich are classified similarly; yet, Miller is directed to an orthopedic device and Jacklich is directed to a dental device. One would not expect a practitioner in the orthopedic arts to look for solutions and designs in the dental arts. The only apparent motivation for combining the references arises from the claimed invention itself, which constitutes hindsight motivation and cannot be relied upon as a reason to combine references.

For at least these reasons, Applicant respectfully submits that the cited references, taken alone or in combination, fail to disclose Applicant's claimed invention. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

III. Newly Added Claims 29-32 are Patentable Over the Cited References

Newly added Claim 29 recites a system for percutaneous delivery of bone cement during a surgical procedure, comprising: a plunger assembly, comprising: a

shaft having a first end, a middle section, and a second end; and a handle attached to the first end of the shaft; a dispenser hub assembly disposed around the shaft, the dispenser hub assembly having a collar and a hand-grip attached to the collar; and a hollow tube for containing the bone cement during the surgical procedure having a first end and a second end, the first end of the hollow tube adapted to be removably engaged with the dispenser hub assembly, wherein the shaft is axially displaceable through the hollow tube for controlled displacement of the bone cement through the second end of the hollow tube.

Newly added Claim 30 recites a system for percutaneous delivery of bone cement during a surgical procedure, comprising: a plunger assembly, comprising: a shaft having a first end, a middle section, and a second end, wherein the middle section is threaded; and a handle attached to the first end of the shaft; a dispenser hub assembly around the shaft, the dispenser hub assembly having a collar and a hand-grip attached to the collar, and a threaded portion formed on an interior surface of the collar; and a hollow tube for containing the bone cement during the surgical procedure having a first end and a second end, the first end of the hollow tube adapted to be removably engaged with the threaded portion of the dispenser hub assembly, wherein the hollow tube includes a funnel-shaped opening at the first end for facilitating the receipt of the bone cement in the hollow tube, and wherein the shaft is axially displaceable through the hollow tube for controlled displacement of the bone cement through the second end of the hollow tube. Claims 31-32 depend from Claim 30 and include at least all of the limitations recited therein.

Taken alone, or in combination, neither Box nor Miller suggest the subject matter claimed in Claims 29 and 30. There is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify or combine Box and/or Miller. First, the Examiner does not provide any authority in Box to combine with the device disclosed in Miller, and vice versa. Second, the two references are directed to entirely different medical fields. Box is directed to a device for inflating and deflating a balloon in a patient's vessels during an angioplasty procedure. See Box, Col. 1, ll. 8-65. Miller is directed to a device for injecting hard tissue implant materials. See Miller, Col. 1, ll. 5-10. The subject matter disclosed in the two references are so distinct that each is classified in an entirely different sub-class at the Patent Office. One would not expect a practitioner in the cardiology arts to look for solutions and designs in the orthopedic arts.

Further, with respect to Claim 30, although Miller discloses an apparatus having a funnel section **52**, there is not a reasonable expectation of success in the combination of Box and Miller. Box discloses a syringe assembly designed to provide the requisite mechanical advantage for inflating a balloon catheter to higher pressures, such as on the order of 450 psi and above. See Box, Col. 1, ll. 46-64. Miller provides a vessel having a funnel section **52** that includes outer threads **32** for receiving the second column **36**. See Miller, Col. 8, ll. 34-43. However, Miller teaches that the mechanical advantage of this arrangement is "not the most powerful possible." *Id.* Miller discloses that when a greater mechanical advantage is required, a device with an introduction section **24** only slightly larger than the bore of the vessel section **28** and piston head **26**

or seal **50** is used. See Miller, Col. 8, ll. 44-60; Fig. 6. When this greater mechanical advantage is required, the funnel section **52** is not integral with the vessel. Id. As such, Miller actually teaches away from a device that combines the features of Box and the funnel section **52** disclosed in Miller. Accordingly, the Examiner's proposed combination of Box and Miller would impermissibly render Box unsatisfactory for its intended purpose. See M.P.E.P. § 2143.01.

For at least these reasons, Applicant respectfully submits that the cited references, taken alone or in combination, fail to disclose Applicant's claimed invention, including newly added Claims 29-32. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

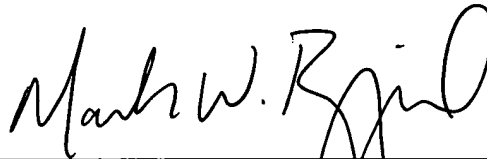
IV. Conclusion

Applicant respectfully submits that the Claims of the present invention define patentable subject matter and that the application is in condition for allowance. Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned attorney at the below listed telephone number.

It is believed that no fee is required for the present amendment. In the event that a fee is required, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to deposit account number 03-2469. Moreover, if the deposit account contains insufficient funds, the Commissioner is hereby invited to contact Applicant's undersigned representative to arrange payment.

Respectfully submitted,

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